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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,790	05/25/2001	Hiroyuki Ebinuma	01307/HG	3337

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EXAMINER

COLE, MONIQUE T

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

<b>Office Action Summary</b>	<b>Application No.</b> 09/856,790	<b>Applicant(s)</b> EBINUMA ET AL.	
	<b>Examiner</b> Monique T. Cole	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a correlation step between the recited steps of the method and the preamble of the claim. For instance the additional step of claim 1 may read "... , wherein a decrease in color development correlates to a specific amount of hydrogen sulfide or sulfide ions as compared to a color chart." This language is only being used for exemplary purposes. Further correction is required.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 4 & 5 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,107,100 to Dabovic (herein referred to as "Dabovic").

Dabovic teaches a method for quantitatively determining a sulfur-containing analyte comprising: combining the analyte with a Zn-hydroxide compound (metal compound) and a nitroprusside (metal indicator/chromophore); and determining the degree of resultant color formation. The analyte may be homocysteine wherein an additional compound may be used to further reduce the homocysteine prior to determination. This step will facilitate the formation of hydrogen sulfide ions. Col. 5, lines 41-47, explicitly details measuring thiol formation (contains hydrogen sulfide ions) by combining zinc and nitroprusside with a homocysteine sample and noting a degree of color formation. At numerous other instances, the specification details measuring the absorbance of said color formation. See abstract; col. 2, lines 20-29; col. 3, lines 55-58; col. 4, lines 20-35, 43-60; col. 5, lines 33-60; col. 8, claims.

3. Claims 4, 7 & 11 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 5,985,540 to Tan et al. (herein referred to as "Tan").

Tan teaches using an enzyme (homocysteinase) to break down either homocysteine or cysteine into  $H_2S$  and treating with a metal compound (ferric chloride) and a metal indicator (NDPD) to produce a color reaction and measuring with a spectrophotometer (col. 25, lines 52-54 and col. 26, lines 18-44). Tan teaches that the concentration of the color compound produced is reflective of  $H_2S$  produced.

#### *Response to Arguments*

4. Applicant's arguments filed 7/16/2004 have been fully considered but they are not persuasive.

Applicant has made several arguments disputing the application of Dabovic as a 35 USC 102(b) reference against claims 1, 2, 4 and 5. Namely, Applicant has argued that (1) in contrast to the presently claimed invention, thiol-chemicals are the object analyzed in Dabovic; (2) Na-nitroprusside itself does not develop color and it has not been shown that it exhibits any specificity to react with metal ions. So it is not categorized as a metal indicator; (3) the mode of colorimetric measurement is different; (4) the principle of Applicant's claimed invention is different from Dabovic where a Zn-slurry is necessitated; and (5) the Dabovic reaction does not produce sulfide ions.

Regarding Applicant's first argument, it is the Examiner's position that the quantitative determination of hydrogen sulfide and/or sulfide ions is inherent in Dabovic's invention. As a result of the reduction of the disulfides to the thiol state, hydrogen sulfide ions are released. Thus, while the Dabovic reference is directed to the detection of cysteine/homocysteine levels, the presence of hydrogen sulfide ions is directly proportional to the reduction & quantification of cysteine/homocysteine.

With regard to Applicant's second argument, the Examiner does not agree that Na-nitroprusside cannot be used as a colorimetric metal indicator. Applicant's attention is directed to col. 1, lines 51-53 where nitroprusside is again used within a colorimetric sulfur detecting procedure. Further, it is also conventionally known to use Na-nitroprusside as colorimetric indicator. Thus, absent any evidence to the contrary, Na-nitroprusside will be considered the colorimetric metal indicator in the instant case. It is noted that Applicant has cited a definition of a metal indicator, but no citation is provided nor is the definition expressly applicable to Na-

nitroprusside. It should be further noted that arguments of counsel cannot take the place of evidence in the record. See MPEP 716.01(c).

In response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., different mode of colorimetric measurement & Zn-slurry is not necessitated) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding Applicant's last argument that the Dabovic reaction does not produce sulfide ions, the Examiner has amended the rejection to instead state that the reaction produces hydrogen sulfide ions. Thus, Applicant's argument is moot.

Regarding the application of the Tan reference, again Applicant has not provided any evidence for his assertion beyond the submitted definition of a metal indicator. However, it is the Examiner's position that NPPD can be used as a colored metal complex, absent any evidence to the contrary. With regard to the state of the reaction system (i.e., pH), the feature upon which Applicant relies is not recited in the rejected claims.

*Allowable Subject Matter*

5. Claims 3, 6, 8-10 & 12-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Monique T. Cole  
Examiner  
Art Unit 1743

MC